K111836

SEP 16 2011

Section 5: 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Corey Jaseph, RAC
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4420, 801-553-4420
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Date Summary Prepared:	15 SEP 2011

II. Name of the Device

Trade Name:	PermaShade Veneer Cement
Common Name:	Dental Cement
Device Classification:	2
Classification Product Code:	EMA
Regulation No.	872.3275 (dental cement)

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate devices are PermaFlo, manufactured by Ultradent (K974413), and Variolink Veneer, manufactured by Ivoclar Vivadent (K931309).

IV. Device Description:

PermaShade Veneer Cement is a light-cured, moderately viscous, permanent resin cement. It is 66.5% filled by mass, is available in four shades, and has very low shrinkage and color change properties.

V. Statement of intended use:

PermaShade Veneer Cement can be used for the permanent cementation of porcelain, zirconia, composite, and other indirect veneers.

VI. Comparison of technological characteristics

Table 5-1: Substantial equivalence comparison

Characteristic	PermaFlo Ultradent K974413	Variolink Veneer Ivoclar Vivadent K931309	PermaShade Veneer Cement Ultradent NEW DEVICE
Intended Use	PermaFlo can be used for: 1. Anterior and posterior restorations, such as Class I, II, III, IV, and V 2. Luting translucent inlays and onlays. 3. Direct veneers and other restorative procedures. 4. Restoring missing subgingival tooth structure prior to endodontic procedures (this is referred to as the "donut" technique)	Adhesive luting of ceramic and composite restorations	Permanent cementation of indirect porcelain, zirconia, and composite veneers
Intended user	Dental professional	Same	Same
Composition of materials	Dimethacrylate-based, filled resin	Same	Same
Type of cure	Photochemical	Same	Same
Percent Fill	68% (m/m)	47 – 66% (m/m)	66% (m/m)
Filler Particle Size	Average 700 nm	40 – 300 nm	13 – 700 nm
Delivery system	Syringe	Same	Same
Multiple Shades	Yes	Same	Same
Physical properties	Tested and characterized according to ISO 4049	Same	Same
Biocompatibility	Tested per ISO 10993-1 and ISO 7405	Same	Same

PermaShade Veneer Cement was designed to be a strong and esthetic option with high color stability for cementing indirect veneers. PermaShade Veneer Cement is a similar material used in the same way by the same types of users as the identified predicate devices, introducing no new safety or efficacy questions. It has been tested against the predicates listed above as outlined in ISO 4049 and demonstrated equivalent in vitro

performance. Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. In summary, this submission demonstrates that PermaShade Veneer Cement is safe and effective and performs equivalently to the identified predicates for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Corey Jaseph
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

SEP 16 2011

Re: K111836
Trade/Device Name: PermaShade Veneer Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: June 28, 2011
Received: June 29, 2011

Dear Ms. Jaseph:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Statement of Indications for Use

510(k) Number (if known): K111836

Device Name: PermaShade Veneer Cement

Indications for Use: PermaShade Veneer Cement can be used for permanent cementation of porcelain, zirconia, composite and other indirect veneers.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111836

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(Posted November 13, 2003)